UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT TOWNSEND, Plaintiff, v. ALEX AZAR, in his official capacity as Secretary of the United States Department of Health and Human Services, Defendant.	Case No. 20 Civ. 1210 (ALC)

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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Plaintiff's Memorandum of Law in Opposition to Defendant's Motion for Summary Judgment ("Plaintiff's Opposition" or "Pl. Opp.") does nothing to alter the conclusion that Defendant's motion should be granted. First, Plaintiff lacks standing. Plaintiff's arguments to the contrary are directly foreclosed by Supreme Court precedent. Second, collateral estoppel does not apply to ALJ[1] decisions such as the one at issue here. Moreover, even if collateral estoppel were not categorically inapplicable in this context, the elements of collateral estoppel are not met. Finally, while appearing to argue that Plaintiff's case should not be dismissed if the Court rejects his collateral estoppel argument, Plaintiff makes no effort to rebut Defendant's argument that Defendant is also entitled to summary judgment on the merits of Plaintiff's claims. Accordingly, Defendant is entitled to summary judgment and Plaintiff's case should be dismissed.

ARGUMENT[2]

I. Plaintiff Lacks Standing

As discussed in Defendant's Memorandum of Law in Support of His Motion for Summary

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[1] Unless otherwise specified, abbreviations and acronyms have the meanings set forth in Defendant's prior briefs (Dkt. Nos. 21 & 25.)

[2] Plaintiff contends that Defendant's motion for summary judgment "may be denied" solely on the ground that Defendant did not provide a statement of undisputed facts pursuant to Local Rule 56.1, and that, alternatively, Plaintiff's asserted facts "may be deemed admitted." (Pl. Opp. at 1.) In fact, as explained in Defendant's Memorandum of Law in Opposition to Plaintiff's Motion for Summary Judgment ("Defendant's Opposition" or "Def. Opp."), courts in this circuit have repeatedly recognized that a Rule 56.1 statement is not appropriate in cases in which, like this one, review is limited to the administrative record. (*See* cases cited Def. Opp. at 3-4.) Accordingly, the fact that Defendant did not submit a Rule 56.1 statement is not a basis for deeming Plaintiff's asserted facts admitted, much less denying Defendant's motion for summary judgment. *See Brodsky v. U.S. Nuclear Regulatory Comm'n*, No. 09-cv-10594 (LAP), 2015 WL 1623824, *3 (S.D.N.Y. Feb. 26, 2015) (in record review case, rejecting contention that agency's "failure to file a Local Rule 56.1 Statement of Undisputed Facts is a fatal procedural defect" and affirming that the "record before the Court is complete and appropriate for a summary judgment ruling"). If the Court nevertheless believes a Rule 56.1 statement is required, Defendant respectfully requests leave to submit one and/or to make such further application as he may consider appropriate.

Judgment ("Defendant's Motion" or "Def Mot."), ALJ Butler did not find Plaintiff responsible for the cost of the TTFT device for the period for which coverage was denied, and Plaintiff thus has not suffered an injury in fact sufficient to confer standing. (Def. Mot. at 10.) Plaintiff does not dispute that he has not suffered any financial injury, but contends that he nonetheless has standing because "he has been denied his statutory right to Medicare benefits" which "in and of itself, confers an injury." (Pl. Opp. at 2.)

The Court rejected this precise argument in *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540 (2016), in which it held that "a bare procedural violation, divorced from any concrete harm, [cannot] satisfy the injury-in-fact requirement of Article III." *Id.* at 1549. The Court clarified its earlier statement in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), that Congress may "'elevat[e] to the status of legally cognizable injuries concrete, *de facto* injuries that were previously inadequate in law,'" clarifying that "Congress' role in identifying and elevating intangible harms does not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right" because "Article III standing requires a concrete injury even in the context of a statutory violation." *Spokeo*, 136 S. Ct. at 1549 (quoting *Lujan*, 504 U.S. at 578); *see also Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1619-20 (2020) (plaintiffs did not have standing notwithstanding the fact that ERISA afforded them a cause of action to sue because they would receive the same payments whether they won or lost).

Plaintiff does not cite *Spokeo* (or any other recent case) and instead attempts to rely on three much older cases: *Warth v. Seldin*, 422 U.S. 490 (1975), *Linda R.S. v. Richard D.*, 410 U.S. 614 (1973), and *Heckler v. Ringer*, 466 U.S. 602, 620 (1984). Those cases also do not support Plaintiff's argument, however. In *Warth*, the Court specifically noted that while "Congress may

grant an express right of action to persons who otherwise would be barred by prudential standing rules . . . Article III's requirement remains: the plaintiff still must allege a distinct and palpable injury to himself." 422 U.S. at 501. With respect to *Linda R.S.*, Plaintiff relies on a single sentence of dicta in a footnote—which also does not purport to dispense with the requirement that a plaintiff suffer an actual injury for purposes of standing. 410 U.S. at 617 n.3. In *Heckler*, the plaintiffs, Medicare claimants, challenged the Secretary's ruling that the type of surgery they had undergone was not reasonable and necessary, and the Court held that it lacked jurisdiction because the plaintiffs had not satisfied the exhaustion requirements set forth in 42 U.S.C. § 405(g) and effectively sought an advisory opinion. 466 U.S. at 621-27. Again, nothing in *Heckler* suggests that a beneficiary has standing to challenge a claim denial in the absence of any actual injury. Similarly, in another case in which Plaintiff's counsel made the identical arguments regarding standing on behalf of another beneficiary, the District Court for the Central District of California recently rejected those arguments and dismissed the case, holding that the plaintiff lacked standing. *See Pehoviack v. Azar*, Case No. 8:20-cv-00661 (DOC) (KES), July 22, 2020, Order (Dkt. No. 22).[3]

Plaintiff's argument that he has standing because there is a chance that he "may be personally liable" on future claims (Pl. Opp. at 3) fares no better. To establish standing in this case, Plaintiff must show that he has suffered or is threatened with an injury that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo*, 136 S. Ct. at 1548. The possibility of future harm does not suffice. *See Clapper v. Amnesty Int'l USA*, 568 U.S.

[3] The district court decisions cited in Plaintiff's brief (Pl. Opp. at 3) all predated *Spokeo*, and, to the extent they suggest that a procedural violation is alone sufficient to confer standing, are inconsistent with that case.

398, 409 (2013) (alleged "injury must be certainly impending to constitute injury in fact . . . allegations of possible future injury are not sufficient" (internal quotation marks omitted)). Plaintiff's claim that he may have to pay claims in the future is entirely speculative—it will only come to pass if (i) Plaintiff has future claims; (ii) those claims are denied; and (iii) Plaintiff, as opposed to the supplier, is held liable for those payments. With respect to the last event, Plaintiff posits that Novocure could become a "participating" provider and ask him to sign an advance beneficiary notice in order to avoid future liability. Such a prediction is plainly based purely on speculation about possible future events. The speculative nature of Plaintiff's purported injury is highlighted by the fact that, while Plaintiff has submitted claims since the denial at issue, those claims have been granted. (*See* Dkt. No. 18 at 12.) Thus, Plaintiff's stated possible future harm does not suffice to establish an injury in fact.

Accordingly, Plaintiff has not established standing, and his case should be dismissed.

II. The Common Law Doctrine of Collateral Estoppel Is Inapplicable[4]

As discussed in Defendant's Motion and Defendant's Opposition, collateral estoppel is inapplicable, both because it is contrary to the statutory and regulatory scheme at issue and because the elements are not met. Plaintiff's Opposition does nothing to alter this conclusion.

First, as Plaintiff recognizes, the Supreme Court held in *Astoria Federal Savings and Loan Association v. Solomino*, 501 U.S. 104 (1991), that collateral estoppel is inapplicable to agency

[4] Plaintiff's arguments that the Court should rely on materials outside of the administrative record as well as later-issued decisions (Pl. Opp. at 4-6) were addressed in Defendant's prior submissions. (*See* Def. Opp. at 4-6.) Plaintiff now makes the additional argument that, despite the fact that two of the favorable ALJ decisions he relies on were not before ALJ Butler, "at the time the Council made the decision to let ALJ Butler's decision stand (by failing/refusing to issue its own decision), the Council knew of the fact of" the other decisions. (Pl. Opp. at 7.) This argument makes no sense—the Council did not make any decision because Plaintiff elected to proceed to federal court (*see* Def. Mot. at 8), so Plaintiff cannot rely on what the Council purportedly knew.

decisions when it would be contrary to legislative intent. *Id.* at 106-108. Plaintiff does not meaningfully dispute that the Medicare regulations are inconsistent with the application of collateral estoppel in this context, but contends that they "have no relevance" because they "are not statutes." (Pl. Opp. at 9.)[5] This erroneous position ignores the broader statutory and regulatory scheme at issue, and Plaintiff is, in any event, mistaken that only a statute—and not regulations—can overcome a common law default rule.

While the cases Plaintiff cites happen to discuss the circumstances in which a statute abrogates a common law principle (*see* cases cited at Pl. Opp. at 7-8), the same analysis applies when the question is whether a regulation abrogates a general common law rule. *See, e.g.*, *Fox Ins. Co., Inc. v. Ctrs. For Medicare & Medicaid Servs.*, 715 F.3d 1211, 1224 (9th Cir. 2013) (citing an identical standard for determining whether a regulation abrogates common law); *ABN Amro Bank N.V. v. United States*, 34 Fed. Cl. 126, 131-32 (1995) ("Because properly promulgated substantive federal regulations have the force of federal law," the same approach employed in determining whether a statute abrogates common law "is equally applicable to a question of whether a set of federal regulations has superseded a rule of federal common law"); *Noble Energy, Inc. v. Jewell*, 110 F. Supp. 3d 5, 13-15 (D.D.C. 2015) (applying same principles applicable to statutes in determining whether regulations abrogated common law rule). The cases Plaintiff cites do not suggest otherwise.

At any rate, both the Medicare statute and regulations are inconsistent with the application

[5] Plaintiff's brief later includes a short section arguing that Defendant's discussion of the Medicare regulations is "difficult to follow" and arguing that "precedential" and "collateral estoppel" are distinct legal concepts. (Pl. Opp. at 16-17.) As discussed in Defendant's prior submissions, the Medicare regulations make clear that an individual ALJ decision is not intended to have preclusive effect—either for the same litigants or others. (*See* Def. Mot. at 11-13; Def. Opp. at 8-9.)

of collateral estoppel to ALJ decisions in this context. "[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute preserves this discretion, leaving it to the Secretary whether to proceed based on individual claim determinations or set out more general rules. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984) ("The Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." (citing 42 U.S.C. § 1395ff(a))); *Almy v. Sebelius*, 679 F.3d 297, 303 (4th Cir. 2012) ("The Medicare statute preserves this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process."). As an exercise of this discretion, the Secretary has elected to proceed based on individual adjudication, and has promulgated regulations to that effect. (*See* Def's Mot. at 3-6 (describing regulatory scheme).) Those regulations make clear that ALJ decisions do not have preclusive effect. *See* 42 C.F.R. § 401.109; *id.* § 405.1062(b). *See Christenson v. Azar*, Case No. 20 Civ. 194, July 6, 2020, Decision and Order (Dkt. No. 21 at 13) (granting Secretary's motion for summary judgment on issue of whether collateral estoppel applies to ALJ decisions regarding claims for TTFT device, reasoning that "[i]n delegating the authority to HHS to oversee an internal review of Medicare determinations, Congress afforded the Secretary the discretion to decide where issue preclusion applies" and "[t]he Secretary's position and its regulations determining when decisions are binding on the same parties in the future are not an unreasonable abuse of its discretion to carry out this task").

Applying preclusive effect to ALJ decisions would also be contrary to the Medicare statute's directive that the Medicare Appeals Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a *de novo* review, but would instead be bound to accept the prior conclusions of any ALJ deciding a claim for any time period. *See Almy*, 679 F.3d at 310 (holding that Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below"). Because in this administrative context each claim for coverage is subject to individual adjudication, *see* 42 U.S.C. § 1395y(a), the circumstance is not, as Plaintiff suggests, comparable to a court reviewing a lower-level court decision *de novo*—in effect, a single favorable ALJ decision at any time would prevent the Medicare Appeals Council from exercising *de novo* review.[6] Binding the Secretary to approve all of Plaintiff's future claims for TTFT—which is, in effect, the relief he requests—would also be contrary to the Medicare Act's (statutory) presentment and channeling requirements. (*See* Def. Mot. at 18-20.)[7]

Plaintiff is also mistaken that the elements of collateral estoppel are met here. As discussed

[6] Plaintiff's Opposition cites a District of Nebraska decision that he contends supports his argument for collateral estoppel in this case. *See DeWall Enters., Inc. v. Thompson*, 206 F. Supp. 2d 992 (D. Neb. 2002). In that case, the plaintiff, a device manufacturer, challenged inconsistent interpretations as to which procedure code it should use to bill for its device, which had led it to be repeatedly accused of using improper billing codes and subject to claims for overpayment. *Id.* at 994-1002. That circumstance is not comparable to that at issue here.

[7] Plaintiff denies that he is seeking any prospective relief, contending that he "only seeks relief for the denied claims that are at issue in this case." (Pl. Opp. at 20.) Plaintiff also contends, however, that unless the Secretary can show "changed circumstances," if Plaintiff prevails in this case he will be entitled to coverage on all future TTFT claims. (Pl. Opp. at 18.)

in Defendant's prior submissions, the earlier ALJ decisions referenced by Plaintiff did not involve the identical issue as in this case, because each decision was explicitly limited to coverage for a specific period of time. (Def. Mot. at 20-21; Def. Opp. at 11.) Plaintiff argues that the Court should conclude that the identical issue was decided in the other ALJ decisions unless the Secretary shows that there is a "material difference between TTFT coverage for Mr. Townsend" for the different periods (Pl. Opp. at 11). Those ALJs did not, however, consider whether Plaintiff's circumstances had changed because each ALJ was limited to determining whether to allow coverage for the specific time period at issue. Simply put, the Secretary has no obligation to point to evidence not considered by the other ALJs or to prove that Plaintiff's circumstances have changed materially since those decisions were issued.

The third element of collateral estoppel also is not met because the Secretary did not have a full opportunity to litigate the issue; as discussed in Defendant's prior submissions, it simply is not feasible for the Secretary to participate in each of the thousands of Medicare claims appeals filed each year in order to preserve the opportunity to challenge an adverse decision. (*See* Def. Mot. 21-23; Def. Opp. at 11-12.) This is true despite Plaintiff's quibble that the number of ALJ appeals filed in FY 2019 (43,887) is slightly lower than the number filed in FY 2018 (approximately 60,000). (*Compare* Pl. Opp. at 21-21 *to* Def. Mot. at 22.)[8] And Plaintiff's discussion of the fourth element (Pl. Opp. at 14-15) is misleading—while each ALJ had to decide whether the TTFT device was "medically reasonable and necessary" for the particular time period at issue, the ALJs did not have to, and did not, decide whether the TTFT device would be

[8] As discussed in Defendant's Opposition, Plaintiff's assertion that the Secretary can appeal an ALJ's decision whether or not it participated in the hearing before the ALJ (Pl. Opp. at 22) is erroneous. (*See* Def. Opp. at 2-3.)

"medically reasonable and necessary" for other time periods in perpetuity.

Finally, Plaintiff's efforts to distinguish the cases cited by Defendant (Def. Mot. at 15-18) (*see* Pl. Opp. at 17-19) are unavailing. As indicated, the cited cases rejected similar attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals; Defendant did not represent that those cases involved the identical issue raised here.[9]

III. Plaintiff's Remaining Claims Fail

Plaintiff concludes his Opposition with an argument that "[t]o the extent the Secretary seeks to put Mr. Townsend to his burden [of] proof on each of his claims . . . , this Court should reject the Secretary's request." (Pl. Opp. at 24.) This is an administrative record case that is to be decided on summary judgment, *see, e.g., Cty. of Westchester v. U.S. Dep't of Housing & Urban Development*, 116 F. Supp. 3d 251, 275-76 (S.D.N.Y. 2015), and Defendant has, in fact, moved for summary judgment on all of Plaintiff's claims. (*See* Def. Mot. at 24-25.) Plaintiff has not provided any support for the proposition that the Court should nonetheless refuse to issue a ruling on any issue other than collateral estoppel.[10] In fact, in light of Plaintiff's failure to make any argument in response to Defendant's motion for summary judgment with respect to issues other

[9] Plaintiff does not provide any support for the assertion that the Provider Reimbursement Review Board ("PRRB"), which was at issue in some of the cases, does not act in a "judicial capacity" (Pl. Opp. at 18). The PRRB is in fact "an administrative review panel that has the power to conduct an evidentiary hearing and affirm, modify, or reverse the intermediary's [reimbursement] determination." *See St. Michael's Medical Ctr. v. Sebelius*, 648 F. Supp. 2d 18, 22-23 (D.D.C. 2009) (citing 42 U.S.C. § 1395oo(a)-(b)). Accordingly, Plaintiff's assertion that it does not act in a judicial capacity is wrong.

[10] Since this case is to be decided on summary judgment, it is not clear how Plaintiff is proposing the Court handle Plaintiff's remaining claims if the Court does not grant Plaintiff's motion on the issue of collateral estoppel. To the extent Plaintiff is suggesting that he be given an opportunity to argue those issues later through additional rounds of summary judgment briefing, there is no reason for such an inefficient approach. In any event, Defendant has moved for summary judgment on all issues and those issues must therefore be decided.

than collateral estoppel, Plaintiff has waived any such arguments and Defendant's motion should be granted as to those issues. *See, e.g.*, *Simon v. City of New York*, 14-CV-8391 (JMF), 2017 WL 57860, at *5 n.5 (S.D.N.Y. Jan. 5, 2017) (failure to respond to argument for summary judgment on issue waives claim).

In any event, Plaintiff's claims fail on the merits. First, the majority of Plaintiff's claims are asserted under the Administrative Procedure Act ("APA"). (*See* Compl. Counts II-VI.) As discussed in Defendant's Motion, the APA does not apply here because judicial review is pursuant to 42 U.S.C. § 405(g). (*See* Def. Mot. at 24-25.) The Second Circuit case Plaintiff cites does not suggest otherwise—it merely indicates that where Section 405(g) does not provide for judicial review in a particular context, judicial review is pursuant to the APA. *See Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 78-86 (2d Cir. 2006) (emphasis added) (applying APA to challenge to validity of Medicare manual provision because no provision of Section 405(g) was on point). Here, Section 405(g) provides for review of the decision at issue under the substantial evidence standard, so APA review is inapplicable. At any rate, whether the APA applies is largely irrelevant because Plaintiff has not set forth any basis for the Court to conclude that ALJ Butler's decision was "unlawfully withheld or unreasonably delayed"; "arbitrary and capricious, [an] abuse of discretion, [or] not in accordance with law"; "in excess of statutory jurisdiction, authority, or limitations or short of statutory right"; or "without observance of procedure required by law." (Compl. at 7-8.) There is also no basis for the Court to conclude that ALJ Butler's decision was not supported by substantial evidence pursuant to Section 405(g). (*See* Def. Mot. at 25.)

CONCLUSION

For the reasons discussed above and in Defendant's prior briefs, Defendant's motion for summary judgment should be granted and Plaintiff's claims dismissed.

Dated: August 3, 2020
New York, New York

Respectfully submitted,

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